UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE FIBROGEN SECURITIES LITIGATION

Case No. 21-cv-02623-EMC

PUBLICLY FILED (UNSEALED)

ORDER GRANTING IN PART PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

Docket No. 149

I. INTRODUCTION

This case is a securities fraud class action brought on behalf of investors who purchased stock in FibroGen, Inc., from December 20, 2018 to July 15, 2021 (the proposed "Class Period"). Pending before the Court is Plaintiffs' motion for class certification. Plaintiffs bring this case against FibroGen and its current Chief Executive Officer Enrique Conterno, former Interim Chief Executive Officer James Schoeneck, former Chief Medical Officer K. Peony Yu[1], current Chief Medical Officer Mark Eisner, and former Chief Financial Officer Pat Cotroneo[2] (collectively, "Individual Defendants")[3] for violations of Section 10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 promulgated thereunder against the Individual Defendants, for allegedly false

[1] Dr. Yu was the Chief Medical Officer between April 2016 and December 20, 2020. CAC ¶ 23. She retired as CMO on December 20, 2020, but remained as an Executive Advisor until August 24, 2021. *Id.*

[2] Cotroneo served as the Company's CFO from 2008 to September 6, 2021, but remained as an Executive advisor until March 31, 2022. *Id.* ¶ 28.

[3] Neff was the former CEO of FibroGen during the first nine months of the Class Period. He is not named because he died in August 2019. *Id.* at 3 n. 1.

and misleading statements about safety and efficacy data for its flagship drug, Roxadustat ("Roxa"), between December 20, 2018 and July 15, 2021. Defendants oppose class certification, with particular emphasis on the portion of the proposed class period from April 7, 2021 to July 15, 2021.

II. BACKGROUND

The Court's Order denying Defendants' motion to dismiss contains an extensive discussion of the factual background of this case. *See* Docket No. 126. This order incorporates that discussion and provides only a brief overview of the relevant facts. Plaintiff Peifa Xu filed a class action complaint in this Court on April 12, 2021. *See* Docket No. 1. This action is a consolidation of that complaint and other similar actions brought by purchasers of FibroGen securities elsewhere in this district.[4] *See* Docket No. 75. The corrected consolidated class action complaint ("CAC") was filed on November 19, 2021. Docket No. 97.

FibroGen is a biopharmaceutical company whose flagship drug, Roxadustat, is an experimental pill designed to treat anemia in patients with chronic kidney disease ("CKD"). CAC ¶ 4. The current standard of care to treat anemia in CKD patients, Epogen, is only used in severe cases for patients already dependent on dialysis ("DD patients") because it leads to an increased risk of major adverse cardiac events ("MACE"). *Id.* ¶ 3. Epogen is not used on patients with less severe CKD who have just begun dialysis ("incident dialysis" patients) or patients who have not yet started dialysis (non-dialysis or "NDD" patients). *Id.* ¶ 4. Accordingly, the key to securing critical FDA approval for Roxadustat was to demonstrate, through Phase 3 clinical trial data, that Roxadustat was at least as effective as Epogen while avoiding the significant safety issues that prevented Epogen from being used to treat incident dialysis patients and NDD patients. *Id.*

Defendants are alleged to have repeatedly asserted that Roxadustat's Phase 3 trial results showed that the drug was superior to Epogen, and that its safety was comparable to the placebo. *Id.* ¶ 5. This included specific claims that Roxadustat's Phase 3 trial data revealed superior

[4] *Gutman v. FibroGen, Inc.*, No. 3:21-cv-02725-YGR; *Grazioli v. FibroGen*, No. 3:21-cv-03212-CRB; *IBEW Local 353 Pension Plan v. FibroGen, Inc.*, No. 3:21-cv-03396-EJD; *Leonard v. FibroGen, Inc.*, No. 3:21-cv-03370-EMC.

efficacy and safety over Epogen. *Id.* The alleged false and misleading statements generally pertained to: (1) Roxadustat's efficacy and safety, (2) whether Roxadustat would receive a "black box" label (the FDA's most severe safety warning) if approved, (3) the non-inferiority margin FibroGen used in its safety analysis, and (4) expressions of optimism about Roxadustat's potential and the likelihood of FDA approval. *Id.*; *see also* Docket No. 91-2.

A. Corrective Disclosures

Plaintiffs allege that FibroGen's misrepresentations were revealed in a series of corrective disclosures over the course of approximately two years. First, on May 9, 2019, FibroGen issued a press release disclosing topline results from the pooled safety analyses from its Phase 3 Roxadustat trials, including major adverse cardiac event ("MACE") results. In the press release, FibroGen revealed that the largest three patient populations in its Global Phase 3 Program did not meet the requisite statistical threshold to claim that Roxadustat was not inferior to Epogen. In reaction to this disclosure, FibroGen shares fell $9.28 per share, or 20%, to close at $36.39 per share on May 10, 2019, down from $45.67 per share on May 9, 2019. This represented an $800 million decline in the Company's market capitalization. CAC ¶ 263.

Second, on March 1, 2021, FibroGen announced that the FDA would hold an Advisory Committee ("AdCom") meeting to review Roxadustat's NDA, which was a surprising setback late in the FDA approval timeline (well over a year after its initial submission). *Id.* at 5. This was particularly concerning given that the PFUDA date, by which investors expected FDA approval of the drug was March 20, 2021.[5] Plaintiffs allege that an AdCom meeting so close in time to the PFUDA date indicated a problem with the application. CAC ¶ 264. In reaction to the disclosure about the AdCom meeting and delayed PFUDA date,[6] FibroGen's stock price fell $16.18 per share

[5] Under the Prescription Drug User Fee Act, the FDA has a set review period that is typically 10 months to one year starting when the FDA accepts a filing for the approval of a new drug. The last day of that review period is referred to as the "PFUDA date" in reference to the Act. CAC ¶ 66n2. The PFUDA date is the date by which investors expect the FDA to approve or disapprove of the drug. For Roxa, the PFUDA date was initially set for December 20, 2020. CAC ¶ 66. However, on December 18, 2020, FibroGen revealed that the PFUDA date had been pushed to March 20, 2021. *Id.* ¶¶ 73, 264.

[6] The delay of the PFUDA date was announced on December 18, 2020, two days before the original PFUDA date, so Plaintiffs appear to argue that the AdCom being scheduled close in time

over the next two days, or 32%, from a close of $50.53 on March 1, 2021, to close at $34.35 per share on March 3, 2021—representing a $1.48 billion drop in market capitalization. CAC ¶ 264.

Third, on April 6, 2021, FibroGen issued a statement "provid[ing] clarification of certain prior disclosures of U.S. primary cardiovascular safety analyses from the roxadustat Phase 3 program for the treatment of anemia of [CKD]." *Id.* ¶ 265. In the press release, FibroGen noted that its management had become aware of "post-hoc changes to the stratification factors"[7] in Roxadustat's Phase 3 trial results—which allegedly amounted to a manipulation of all nine key analyses after the data had been fully unblinded—and that they needed to clarify this with the FDA. *Id.* at 2, 4, at 5. Based on the actual "prespecified" FDA analyses, FibroGen could not "conclude that Roxadustat reduced the risk of MACE . . . or is superior to . . . [Epogen.]" *Id.* ¶ 8. Specifically, the Company stated that it "cannot conclude that [R]oxadustat reduces the risk of (or is superior to) MACE+ in dialysis, and MACE and MACE+ in incident dialysis compared to [Epogen]." Once Defendants' post-hoc "manipulations" were corrected, Plaintiffs contend that the true data revealed that there were substantial safety concerns—including increased risk of serious afflictions such as thrombosis, seizures, stroke, and even death—that it showed the drug was significantly less effective and less safe than placebo or even Epogen, which already carried the "Black Box" warning. CAC ¶ 7. Plaintiffs contend that, as a result, Roxadustat's true data failed to support FDA approval in any patient population at all, effectively dooming its FDA approval prospects. *Id.*[8] FibroGen's share price dropped almost in half in two days, from $34.64 per share on April 6, 2021, to $18.81 per share on April 8, 2021. *Id.* ¶ 8. On this news, the Company's share price fell over 45% over the next two days, or $15.83 per share, from a close of

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to the March 20, 2021 PFUDA date raised concerns for investors.

[7] "Stratification factors" refer to grouping clinical trial subjects to ensure balance in treatment arms by factors such as by race, sex, geographic location, and other demographic categories.

[8] Defendants contend that the April 6 press release did not say FibroGen had "manipulated" any data. Rather, it informed investors that FibroGen had clarified the CV safety analyses in the Roxadustat NDA with the FDA. FibroGen claims that the "clarification" amounted to an amendment to the analysis by swapping the analysis previously designated as "primary" being redesignated as a "sensitivity analysis," while a different analysis (previously designated as a "sensitivity analysis") coming the "primary analysis." *See* Declaration of Tijana M. Brien ("Brien Decl.") Ex. 17.

$34.64 per share on April 6, 2021, to closing at $18.81 per share on April 8, 2021—representing an approximate $1.45 billion decline in market capitalization. CAC ¶ 265.

Fourth, on July 15, 2021, the AdCom met, and FibroGen announced that committee "voted to recommend not approving [R]oxadustat." At the AdCom meeting, the Committee panel voted virtually unanimously against approval for Roxadustat. The panel voted 13-1 against approval of Roxadustat in non-dialysis CKD patients given the serious and concerning safety signals, particularly mortality. With respect to the DD patients (the population Epogen is used for), the panel voted 12-2 against approval of Roxadustat, with panelists again concerned with the drug's safety profile, in particular the increased risk over Epogen. As a result of this development, trading in FibroGen's stock was halted on July 15, 2021. Plaintiffs contend that this is when the market finally understood the full extent of Defendants' prior misrepresentations concerning Roxadustat's safety profile and the drug's slim prospects for FDA approval. When trading reopened the following day, FibroGen's stock price fell over 42%, or $10.49 per share, from a prior close of $24.84 per share to close at $14.35 per share on July 16, 2021. This represented a loss of approximately $971 million of market capitalization with a volume of over 16 million shares traded. CAC ¶¶ 266-267.

The reason for the stock price drop following the AdCom's vote is disputed. Plaintiffs claim that it was because of factual revelations made at the AdCom meeting that had not previously been disclosed to the market. In their opening brief, Plaintiffs claimed that the undisclosed revelation was that AdCom concluded that FibroGen's undisclosed prespecified sensitivity analyses demonstrated that the drug's efficacy over Epogen was inconclusive at best, and that the drug caused "greater rates of some important adverse events [] than even [Epogen]," including a higher rate of death and other major side effects. Docket No. 149 at 15-16. Defendants then pointed out that the FDA published a briefing document on July 13, 2021, two days before the vote, which contained the underlying data and analyses that would be discussed at the July 15 Advisory Committee meeting, including the "critical prespecified sensitivity analyses." Brien Decl., Ex. 8 at 47, 50-51. That briefing document identified the same non-dialysis dependent hazard ratios identified in the Complaint. Moreover, several analysts published reports

about the FDA's briefing document and the referenced sensitivity analyses that same day. *Id.*, Exs. 9-16. The parties agree that there was not a statistically significant drop in stock price following the July 13, 2021 briefing document was published–aside from the July 16, 2021 decline. Zurek Rep ¶ 19; Deposition of Chad Coffman, Docket No. 179-4, Ex. 2 ("Coffman Depo") at 81:2-23. Therefore, Defendants contend that the July 16, 2021 market reaction cannot be attributed to the July 13 disclosure. Plaintiffs do not argue otherwise. Instead, Plaintiffs attempt to demonstrate that the July 16, 2021 decline in stock price can be attributed to corrective disclosures that became public for the first time during the July 15, 2021 AdCom meeting. On September 15, 2023, the parties submitted a joint supplemental brief regarding these alleged corrective disclosures. *See* Supplemental Brief, Docket No. 221.

In total, FibroGen's stock price lost 75% of its value within the proposed class period, allegedly due to this data manipulation, and never recovered. CAC ¶ 13. Plaintiffs now move to certify a class ("Mot."), Docket No. 147, and submit with their motion several exhibits, including an expert report written by Chad Coffman, CFA, Docket No. 147-2 ("Coffman Rep."). Defendants oppose certification ("Oppo."), Docket No. 179-3, and submit several exhibits, including an expert report written by Dr. Paul Zurek ("Zurek Rep."), Docket No. 179-4, Ex. 1. Plaintiffs' reply ("Repl."), Docket No. 191-2 includes several new exhibits and new arguments relating to the July 16 stock price drop. Consequently, the Court accepted a sur-reply from Defendants, Docket. No. 210-1. The Court held a hearing on August 31, 2023, at which counsel for both parties appeared.

III. LEGAL STANDARD

Although expressly authorized by Rule 23, the "class action is 'an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only.'" *Wal–Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 348 (2011) (quoting *Califano v. Yamasaki*, 442 U.S. 682, 700–01 (1979)). "In order to justify departure from that rule, 'a class representative must be part of the class and possess the same interest and suffer the same injury as [her fellow] class members.'" *Id.* (quoting *E. Tex. Motor Freight Sys., Inc. v. Rodriguez*, 431 U.S. 395, 403 (1977)). Accordingly, before certifying a class, the Court "must conduct a 'rigorous analysis' to determine

whether the party seeking certification has met the prerequisites of Rule 23." *Mazza v. Am. Honda Motor Co., Inc.*, 666 F.3d 581, 588 (9th Cir. 2012) (quoting *Zinser v. Accufix Rsch. Inst., Inc.*, 253 F.3d 1180, 1186, *amended* 273 F.3d 1255 (9th Cir. 2001)). The Supreme Court has made it clear that Rule 23 "does not set forth a mere pleading standard." *Comcast Corp. v. Behrend*, 569 U.S. 27, 33 (2013) (quoting *Wal-Mart*, 564 U.S. at 349). Rather, the party seeking certification must "affirmatively demonstrate" her compliance with the requirements of both Rules 23(a) and 23(b). *See Wal-Mart*, 564 U.S. at 349.

Rule 23(a) permits plaintiffs to sue as representatives of a class if: (1) "the class is so numerous that joinder of all members is impracticable" ("numerosity" requirement); (2) "there are questions of law or fact common to the class" ("commonality" requirement); (3) "the claims or defenses of the representative parties are typical of the claims or defenses of the class" ("typicality" requirement); and (4) "the representative parties will fairly and adequately protect the interests of the class" ("adequacy" requirement). Fed. R. Civ. P. 23(a)(1)-(4). The purpose of Rule 23(a)'s requirements is largely to "ensure[ ] that the named plaintiffs are appropriate representatives of the class whose claims they wish to litigate," and to "effectively limit the class claims to those fairly encompassed by the named plaintiff's claims." *Wal-Mart*, 564 U.S. at 349 (quoting *Gen. Tel. Co. of Sw. v. Falcon*, 457 U.S. 147, 156 (1982)).

If each of the Rule 23(a) requirements are satisfied, the purported class must also satisfy one of the three prongs of Rule 23(b). Here Plaintiffs seek certification under Rule 23(b)(3), which requires the Court to find that "questions of law or fact common to class members predominate over any questions affecting only individual members" ("predominance" requirement), and "that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy" ("superiority" requirement). Fed. R. Civ. P. 23(b).

The underlying merits of the case, while admittedly relevant at the class certification stage, should not overly cloud the Court's certification analysis—the only question presently before the Court is whether the requirements of Rule 23 are met. *See Comcast*, 569 U.S. at 33–34. In considering a motion for class certification, the substantive allegations of the complaint are accepted as true, but "the court need not accept conclusory or generic allegations regarding the

suitability of the litigation for resolution through class action." *Hanni v. Am. Airlines*, No. C-08-00732-CW, 2010 WL 289297, at *8 (N.D. Cal. Jan. 15, 2010).

The fact that certain elements of proof may favor the defendant on the merits does not negate class certification; the issue is whether the proof is amenable to class treatment whether that proof favors plaintiff or defendant. "Neither the possibility that a plaintiff will be unable to prove [her] allegations, nor the possibility that the later course of the suit might unforeseeably prove the original decision to certify the class wrong, is a basis for declining to certify a class which apparently satisfies the Rule." *Blackie v. Barrack*, 524 F.2d 891, 901 (9th Cir. 1975). Indeed, even "after a certification order is entered, the judge remains free to modify it in the light of subsequent developments in the litigation." *Gen. Tel. Co. of Sw.*, 457 U.S. at 160. Ultimately, whether to certify a class is within the discretion of the Court. *See Levya v. Medline Indus. Inc.*, 716 F.3d 510, 513 (9th Cir. 2013); *United Steel, Paper & Forestry, Rubber, Mfg. Energy, Allied Indus. & Serv. Workers Int'l Union, AFL–CIO CLC v. ConocoPhilips Co.*, 593 F.3d 802, 810 (9th Cir. 2010).

IV. DISCUSSION

Plaintiffs define their proposed class as: "themselves and those persons or entities who purchased or otherwise acquired the publicly traded securities of FibroGen, including options, during the period from December 20, 2018 through July 15, 2021, inclusive (the "Class Period"), and were damaged thereby (the "Class")." Mot. at 11:14-16.[9]

Defendants do not contest most elements of the class certification analysis. Rather, they make only three arguments in opposition to Plaintiffs' motion. First, they assert that Plaintiffs are not adequate representatives for the putative class. Opp. 23-25. Second, they argue that, specifically as to the portion of the class period from April 6, 2021 to July 15, 2021, plaintiffs failed to show that common questions of law and fact predominate because Defendants can rebut

[9] Plaintiffs exclude from the proposed class: "(i) Defendants; (ii) members of the immediate families of Defendants; (iii) the subsidiaries and affiliates of Defendants; (iv) any person who is an officer, director, or controlling person of any Defendant; (v) any entity in which any Defendant has a controlling interest; (vi) Defendants' directors' and officers' liability insurance carriers, and any affiliates or subsidiaries thereof; and (vii) the legal representatives, heirs, successors, or assigns of any such excluded party." *Id.* at n.2.

the fraud-on-the-market theory of reliance. *Id.* 3-18. Third, Defendants contend that Plaintiffs failed to articulate a theory of class wide damages that is consistent with their theory of liability. *Id.* 18-23. Though Defendants do not challenge other elements of class certification, the Court addresses each of the necessary elements as part of the "rigorous analysis" required by the Ninth Circuit in *Zinser*, 253 F.3d 1180, 1186.

A. Rule 23(a)

In order to prevail in their motion to certify the class, Plaintiffs must demonstrate that the class satisfies each requirement of Rule 23(a). These requirements are: (1) "the class is so numerous that joinder of all members is impracticable" ("numerosity" requirement); (2) "there are questions of law or fact common to the class" ("commonality" requirement); (3) "the claims or defenses of the representative parties are typical of the claims or defenses of the class" ("typicality" requirement); and (4) "the representative parties will fairly and adequately protect the interests of the class" ("adequacy" requirement). Fed. R. Civ. P. 23(a)(1)-(4).

1. Numerosity

Rule 23(a)(1) requires that "the class is so numerous that joinder of all members is impracticable." Fed. R. Civ. Proc. 23(a)(1). "As the Supreme Court has explained, this 'numerosity requirement requires examination of the specific facts of each case and imposes no absolute limitations.'" *A. B. v. Haw. State Dep't of Educ.*, 30 F.4th 828, 835 (9th Cir. 2022) (quoting *Gen. Tel. Co. of the NW., Inc. v. EEOC*, 446 U.S. 318, 330 (1980)). "Courts within the Ninth Circuit generally agree that numerosity is satisfied if the class includes forty or more members." *Malriat v. QuantumScape Corp.*, No. 3:21-CV-00058-WHO, 2022 WL 17974629, at *3 (N.D. Cal. Dec. 19, 2022).

Courts "'may infer that, when a corporation has millions of shares trading on a national exchange,' the numerosity requirement is met." *In re Twitter Inc. Sec. Litig.*, 326 F.R.D. 619, 626 (N.D. Cal. 2018) (quoting *In re Cooper Companies Inc. Sec. Litig.*, 254 F.R.D. 628, 634 (C.D. Cal. 2009)). Plaintiffs contend that "FibroGen had between 85 and 93 million shares of common stock outstanding during the Class Period with an average weekly trading volume of over 4 million shares." Coffman Report ¶¶ 28, 69. This is sufficient to show the number of putative

class members is so numerous that joinder would be impracticable. *See In Re Twitter Inc. Sec. Litig.*, 326 F.R.D. at 626. FibroGen does not challenge numerosity, and Plaintiffs have satisfied their burden for the numerosity requirement of Rule 23(a).

2. Commonality

"The commonality requirement of Rule 23(a)(2) requires plaintiffs seeking class certification to show that their claims 'depend upon a common contention' that 'is capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke.'" *A. B.*, 30 F.4th at 839 (quoting *Wal-Mart*, 564 U.S. at 350). Plaintiffs "need not show . . . that every question in the case, or even a preponderance of questions, is capable of class wide resolution. So long as there is even a single common question, a would-be class can satisfy the commonality requirement of Rule 23(a)(2)." *Parsons v. Ryan*, 754 F.3d 657, 675 (9th Cir. 2014).

Plaintiffs contend, and FibroGen does not dispute, that the questions of law or fact common to the putative class include whether: (1) Defendants violated the federal securities laws; (2) Defendants misrepresented or omitted material facts; (3) Defendants acted with scienter; (4) the Individual Defendants controlled FibroGen and its violations of the federal securities laws; (5) Defendants' misrepresentations and omissions caused Class members to suffer a compensable loss; and (6) Class members have sustained damages, and the proper measure of damages. Mot. at 19:14-18. These questions depend on common contentions that are capable of class wide resolution and so satisfy commonality. *Cf. In re Intuitive Surgical Sec. Litig.*, 2016 WL 7425926, at *4 (N.D. Cal. Dec. 22, 2016) ("In securities fraud cases . . . courts have easily found commonality where class members all bought or sold the same stock in reliance on the same disclosures made by the same parties."). Accordingly, Plaintiffs have satisfied their burden for the commonality requirement of Rule 23(a).

3. Typicality

"To establish typicality, as required by Rule 23(a)(3), plaintiffs must show that 'the claims or defenses of the representative parties are typical of the claims or defenses of the class.'" *A. B.*, 30 F.4th at 839 (quoting Fed. R. Civ. Proc. 23(a)(3)). "The test of typicality 'is whether other

members have the same or similar injury, whether the action is based on conduct which is not unique to the named plaintiffs, and whether other class members have been injured by the same course of conduct.'" *Id.* (quoting *Hanon v. Dataproducts Corp.*, 976 F.2d 497, 508 (9th Cir. 1992)). "Under the rule's permissive standards, representative claims are 'typical' if they are *reasonably co-extensive* with those of absent class members; they need not be substantially identical." *Amey v. Cinemark USA Inc.*, No. 13-CV-05669-WHO, 2018 WL 3956326, at *4 (N.D. Cal. Aug. 17, 2018) (quoting *Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1020 (9th Cir. 1998)) (emphasis in *Amey*). "Unique defenses against a class representative 'counsel against class certification only where they threaten to become the focus of the litigation.'" *Id.* (quoting *Rodriguez v. Hayes*, 591 F.3d 1105, 1124 (9th Cir. 2010)). "Because the considerations underlying the two requirements overlap considerably, the Supreme Court has noted that '[t]he commonality and typicality requirements of Rule 23(a) tend to merge." *A. B.*, 30 F.4th at 839 (quoting *Falcon*, 457 U.S. at 157 n.13).

Plaintiffs and Class members all purchased FibroGen securities and assert Section 10(b) claims, based on the same misstatements and omissions by Defendants, and Section 20(a) claims of "control person" liability. Mot. at 20:1-5. Typicality is satisfied where "the core factual and legal questions . . . include[e] whether the statements and omissions at issue were material and misleading, and whether the price of [company's] shares was artificially inflated as a result of them, are common to the class, and the lead plaintiffs allege injuries typical of the class." *In re SanDisk LLC Sec. Litig.*, 2018 WL 4293336, at *1 (N.D. Cal. Sept. 4, 2018). Accordingly, Plaintiffs have met their burden on this element. Defendants do not dispute typicality, nor do they claim that Plaintiffs are subject to any "unique defenses" that "threaten to become the focus of the litigation." *In re LendingClub Sec. Litig.*, 282 F.Supp.3d 1171, 1179 (N.D. Cal. 2017).

4. Adequacy

Rule 23(a)(4) requires that the named parties be able to "fairly and adequately protect the interests of the class." Fed. R. Civ. Proc. 23(a)(4). "The adequacy inquiry turns on: (i) whether the named plaintiff and class counsel have any conflicts of interest with other class members; and (ii) whether the named plaintiff and class counsel can vigorously prosecute the action on behalf of

the class." *Amey*, 2018 WL 3956326, at *6 (citing *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 985 (9th Cir. 2011)). A class representative is adequate where her "claim and the class claims are so interrelated that the interests of the Class Members will be fairly and adequately protected in their absence." *Falcon*, 457 U.S. at 157. Defendants argue that depositions of the Lead Plaintiffs here revealed that they are "strikingly unfamiliar with their own allegations" because they could not describe how the alleged data occurred (Docket No. 179-3, Ex. 5 at 75:17-76:7), 99:23-101:18), were unfamiliar with the terms "post hoc" and "stratification factors" and could not explain how they related to the alleged manipulation theory (*Id.*, Ex. 6 at 82:12-83:11, 85:24-88:12), could not answer certain questions about whether FibroGen's pooled cardiovascular data was false (*e.g.*, Ex. 6 at 127:7-128:2; Ex. 5 at 131:24-132:5), and one was not able to name each Defendant. *Id.*, Ex. 5 at 60:3-15.

"[T]he Supreme Court expressly disapproved of attacks on the adequacy of a class representative based on the representative's ignorance, noting that in complex securities litigation such as this case, the named plaintiff need not have specific knowledge of the material facts in support of his claim." *Mulderrig v. Amyris, Inc.*, 340 F.R.D. 575, 583 (N.D. Cal. 2021) (citing *Surowitz v. Hilton Hotels Corp.*, 383 U.S. 363, 370-76 (1966) ("affirming class certification where the named plaintiff knew nothing about the content of the suit but knew she was not getting her stock dividends")). In the Ninth Circuit, a class representative "will be deemed inadequate only if she is 'startlingly unfamiliar' with the case." *Twitter*, 326 F.R.D. at 628. Particularly in complex securities class actions such as this, "it is hardly a badge of inadequacy" to rely heavily on the expertise of attorneys. *In re Facebook Biometric Info. Priv. Litig.*, 326 F.R.D. 535, 543 (N.D. Cal. 2018), *aff'd sub nom. Patel v. Facebook, Inc.*, 932 F.3d 1264 (9th Cir. 2019) (citing *Baffa v. Donaldson, Lufkin & Jenrette Sec. Corp.*, 222 F.3d 52, 62 (2d Cir. 2000)).

It is not necessary that class representatives have a detailed understanding of the technical aspects of the case. Instead, it is sufficient that they have a lay understanding of the basis for the suit and an understanding of their injury. *See, e.g.*, *In re Honest Co. Sec. Litig.*, 2023 WL 3190506, at *7 (C.D. Cal. May 1, 2023). Defendants have not shown that the proposed class counsel is startlingly unfamiliar with their case. Instead, the record supports a finding that each

Lead Plaintiff has a basic understanding of the facts underlying the case, their injury, and their role as a class representative.

For example, Baltimore Employees' representative accurately testified the instant securities class action alleged that FibroGen misled investors by touting its "new drug for patients with anemia and kidney disease" as "a better drug than the . . . injectable drug [] those patients were using," while in truth, "there [were] discrepancies in the testing or results of the testing," which, when revealed, "caused the stock price to plummet." P's Ex. 32 at 214:23-216:4. The Philadelphia Pension Fund's representative gave a similar response, discussing FibroGen's alleged manipulation of Roxa studies to tout its efficacy and safety. P's Ex. 33 at 125:4-16.

Plymouth County's representative likewise described the litigation as relating to FibroGen's attempts to bring Roxa to market through "false and misleading statements" about the drug's safety. P's Ex. 34 at 43:12-44:6. Moreover, each of the Lead Plaintiffs representatives accurately described the Class, Class Period during which Defendants made their allegedly false and misleading statements; the Defendants by either name and/or position; and Lead Plaintiffs' obligations and responsibilities in serving as a class representative. *See* P's Ex. 32 at 42:25-43:8, 59:24-60:24, 216:1-4; P's Ex. 33 at 21:3-6, 77:3-79:8; P's Ex. 34 at 42:21-44:11, 80:14-81:15. Each of these statements is accurate and rebuts Defendants' assertions that the plaintiffs do not understand the case and are simply pawns for their counsel. Accordingly, the adequacy requirements of Rule 23(a)(4) are met.

B. Predominance Under Rule 23(b)(3)

Plaintiffs move for class certification under Rule 23(b)(3).[10] "[F]or the plaintiffs to carry

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[10] Rule 23(b)(3) provides:

> [T]hat the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy. The matters pertinent to these findings include:
>
> (A) the class members' interests in individually controlling the prosecution or defense of separate actions;
>
> (B) the extent and nature of any litigation concerning the controversy already begun by or against class members;

their burden [under Rule 23(b)(3)] of proving that a common question predominates, they must show that the common question relates to a central issue in the plaintiffs' claim." *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 31 F.4th 651, 665 (9th Cir. 2022) (noting plaintiffs have the burden to prove facts that establish FRCP 23(b)(3) factors by a preponderance of the evidence). "Therefore, '[c]onsidering whether "questions of law or fact common to class members predominate" begins, of course, with the elements of the underlying cause of action.'" *Id.* (quoting *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804, 809 (2011) ("*Halliburton I*")).

Here, Plaintiffs allege violations of Section 10(b) and Rule 10b-5 of the Securities Exchange Act, the elements of which are: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation."[11] *Halliburton I*, 563 U.S. at 809-10 (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37-38 (2011)).

1. Reliance

"Whether common questions of law or fact predominate in a securities fraud action often turns on the element of reliance." *Halliburton I*, 563 U.S. at 810. Though reliance can be established "by showing that [the plaintiff] was aware of a company's statement and engaged in as relevant transaction . . . based on that specific misrepresentation," plaintiffs in securities class actions often establish reliance through the "fraud on the market theory" articulated by the Supreme Court in *Basic, Inc. v. Levinson*, 485 U.S. 224 (1988). *See Halliburton I*, 563 U.S. at 810-11.

(C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and
(D) the likely difficulties in managing a class action.

[11] Plaintiffs also allege violations of Section 20(a) of the Exchange Act against individual defendants. Because those allegations are predicated on the 10(b) and 10b-5 allegation, the Court does not separately address this allegation.

a. Presumption of Reliance: Fraud on the Market Theory

The Fraud on the Market theory rests on the idea that "most publicly available information is reflected in market price," and therefore investors "who buy[] or sell[] stock at the price set by the market do[] so in reliance on the integrity of that price." *Basic*, 485 U.S. at 247. Accordingly, rather than require plaintiffs to demonstrate their reliance on the alleged misrepresentations (which may preclude a finding that common issues predominate) as a matter of fact, where the market for securities is "impersonal" and "well-developed," "an investor's reliance on any public material misrepresentations . . . may be presumed." *Id.*; *see also Halliburton I*, 563 U.S. at 811 ("[T]he market price of shares traded on well-developed markets reflects all publicly available information, and, hence, any material misrepresentations." (quoting *Basic*, 485 U.S. at 246)). Under the fraud on the market theory, plaintiffs are entitled to a rebuttable presumption of reliance if they show: "(1) that the alleged misrepresentations were publicly known, (2) that they were material, (3) that the stock traded in an efficient market, and (4) that the plaintiff traded the stock between the time the misrepresentations were made and when the truth was revealed." *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 268 (2014) ("*Halliburton II*") (citations omitted). It is undisputed that the misrepresentations were publicly known and that the plaintiffs traded stock during the relevant time-period. Proving materiality is "not a prerequisite to class certification," *Amgen*, 568 U.S. at 459-60, but in any event, Plaintiffs sufficiently allege it.

To assess whether a market was efficient, the Ninth Circuit refers to the factors outlined in *Cammer v. Bloom*, 711 F. Supp. 1264 (D. N.J. 1989). *See Miller v. Thane Int'l, Inc.*, 615 F.3d 1095, 1102-03 (9th Cir. 2010); *Binder*, 184 F.3d at 1064-65. These factors are: (1) whether the stock trades at a high weekly volume, (2) whether securities analysts follow and report on the stock, (3) whether the stock has market makers and arbitrageurs, (4) whether the company is eligible to file SEC registration form S-3, as opposed to form S-1 or S-2, and (5), whether there are "empirical facts showing a cause and effect relationship between unexpected corporate events or financial releases and an immediate response in the stock price." *Binder*, 184 F.3d at 1065 (quoting *Cammer*, 711 F. Supp. at 1286-87). "The *Cammer* factors set a high bar and demand rigorous analysis." *Purple Mountain Tr. v. Wells Fargo & Co.*, No. 18-CV-03948-JD, 2022 WL

3357835, at *3 (N.D. Cal. Aug. 15, 2022) (citing *Miller*, 615 F.3d at 1103).

Defendants do not object to Plaintiffs' claim to have satisfied the *Cammer* factors and have therefore met their burden on the presumption of reliance. However, Defendants contend that they have met their own burden to rebut the presumption of reliance as to the portion of the class period after April 6, 2021.

i. Weekly Volume

The first *Cammer* factor is the weekly trading volume during the proposed Class Period. *Cammer*, 711 F. Supp. at 1286. A high average trading volume suggests "significant investor interest in the company" and, in turn, a "likelihood that many investors are executing trades on the basis of newly available or disseminated corporate information." *Id.* "Turnover measured by average weekly trading of two percent or more of the outstanding shares would justify a strong presumption that the market for the security is an efficient one" and "one percent would justify a substantial presumption." *Id.*

During the Class Period, FibroGen common stock had an average weekly trading volume of 4.65% of outstanding shares—roughly 4.14 million shares. Coffman ¶ 28. FibroGen's Class Period trading volume far exceeds the 1%-2% *Cammer* threshold, supporting a finding of efficiency. *Id.* ¶ 28 & Ex. 3; *see Purple Mountain Trust v. Wells Fargo & Co.*, 2022 WL 3357835, at *4 (N.D. Cal. Aug. 15, 2022) (an average weekly trading volume of 2% of total shares outstanding "supports a strong presumption of market efficiency)." This factor favors a finding of market efficiency.

ii. Securities Analysts

The second *Cammer* factor, coverage by securities analysts, relates to how new information on the Company was being disseminated and acted upon by investors during the proposed Class Period. *See Cammer*, 711 F. Supp. at 1286. During the Class Period, eight securities firms issued at least 111 analyst reports on FibroGen. Coverage included Jefferies LLC, Mizuho, and Raymond James & Associates. Coffman ¶ 34 & Ex. 4.

Failing to plead that *any* analysts followed or reported on a stock end counsels against finding an efficient market. *See ScripsAmerica, Inc. v. Ironridge Glob. LLC*, 119 F. Supp. 3d

1213, 1254 (C.D. Cal. 2015). But there appears to be "no case that identifies a threshold number of analysts" necessary for this factor to favor market efficiency. *Hayes v. MagnaChip Semiconductor Corp.*, No. 14-CV-01160-JST, 2016 WL 7406418, at *5 (N.D. Cal. Dec. 22, 2016). Courts have found this factor supports market efficiency with as few as four to seven analysts covering a particular stock. *See id.*; *Todd v. STAAR Surgical Co.*, No. CV-14-05263-MWF-RZ, 2017 WL 821662, at *7 (C.D. Cal. Jan. 5, 2017) (six analysts); *See Hayes v. MagnaChip Semiconductor Corp.*, 2016 WL 7406418, at *5 & n.2 (N.D. Cal. Dec. 22, 2016) (coverage by "only four or six analysts" weighs in favor of market efficiency); *Brown v. China Integrated Energy Inc.*, 2015 WL 12720322, at *17 (C.D. Cal. Feb. 17, 2015) (coverage by five analysts "weighs in favor of market efficiency"). Coverage of FibroGen by at least eight securities analysts during the class period supports a finding that analyst coverage supports a finding of market efficiency.

iii. Market Makers and Arbitrageurs

"A market-maker is one who helps establish a market for securities by reporting bid-and-asked quotations (the price a buyer will pay for a security and the price a seller will sell a security) and who stands ready to buy or sell at these publicly quoted prices." *Todd*, 2017 WL 821662, at *7 (quoting *Petrie v. Elec. Game Card, Inc.*, 308 F.R.D. 336, 351 (C.D. Cal. 2015)). The presence of a greater number of market makers supports a stronger inference of liquidity, and therefore a stronger likelihood that the market for that security is efficient." *Id.*; s*ee also Carpenters Pen. Tr. Fund of St. Louis v. Barclays PLC*, 310 F.R.D. 69, 92 (S.D.N.Y. 2015) ("anywhere between six and twenty market makers is sufficient to support a finding of market efficiency"); *Diamond Foods*, 295 F.R.D. at 248 (nineteen market makers sufficient).

Though arbitrageurs are also discussed by *Cammer*, "most courts consider only the number of market makers." *Id.* (first quoting *Petrie*, 308 F.R.D. at 351; and then citing *In re Juniper Networks, Inc. Sec. Litig.*, 264 F.R.D. 584, 591 (N.D. Cal. 2009)). Plaintiffs contend, and Defendants do not refute, that there were over one hundred market makers for FibroGen common stock during the Class Period, thus supporting market efficiency. Coffman ¶ 42. Plaintiffs contend that stock trading on a major exchange, as FibroGen did on NASDAQ, is independently

sufficient to satisfy this *Cammer* factors. Coffman ¶¶ 38-41; *See Vinh Nguyen v. Radient Pharm. Corp.*, 287 F.R.D. 563, 572-73 (C.D. Cal. 2012) (finding stock trading on a major exchange through designated market makers sufficient to support market efficiency). Under either test, this factor favors a finding of market efficiency.

iv. SEC Registration

Form S-3 is an "abbreviated" SEC filing, for which entities are eligible to file if they filed SEC reports for the previous 12 months consecutively and meet certain financial and minimum stock requirements. Form S-3 Eligibility Requirements (I)(A)-(B). *See QuantumScape Corp.* at *7. "[T]he existence of Form S-3 status is an important factor weighing in favor of a finding that a market is efficient." *Cammer*, 711 F. Supp. at 1285. This is because the filing of Form S-3 "is predicated on the Commission's belief that the market operates efficiently" for the company. *Id.* at 1284; *see In re NII Holdings, Inc. Sec. Litig.*, 311 F.R.D. 401, 411 (E.D. Va. 2015) ("[W]hen an issuer of securities meets Form S-3's requirements, the market for its securities is likely one that quickly assimilates material public information into the price because the market is well developed and trading is robust."). Here, prior to, during, and after the Class Period, FibroGen filed Form S-3ASRs, and met the eligibility criteria for filing a Form S-3 throughout the Class Period. Coffman ¶ 45; *Diamond Foods*, 295 F.R.D. at 248 (describing significant threshold requirements for Form S-3 eligibility which "tends to support a finding of efficiency"); *In re Countrywide*, 273 F.R.D. at 613 n.82 (noting traditional prominence of S-3 filing eligibility as an important *Cammer* factor). This factor favors a finding of market efficiency.

v. Cause and Effect Relationship

The fifth and final *Cammer* factor is whether there is evidence that the price of a security regularly reacts to unexpected corporate events or the issuance of financial releases about the issuer. *See Cammer*, 711 F. Supp. at 1287. The presence of such a reaction is strong evidence of an efficient market. *Id.* Of the factors courts consider, the cause and effect relationship is the most direct measure of market efficiency. Some courts have found that where the first four *Cammer* factors and the three *Krogman* factors are satisfied, it is not necessary for a court to consider *Cammer* factor five. *See, e.g., In re Vale S.A. Sec. Litig.*, 2022 WL 122593, at *8

(E.D.N.Y. Jan. 11, 2022), *report and recommendation adopted*, 2022 WL 969724 (E.D.N.Y. Mar. 31, 2022) ("[I]f the first four *Cammer* factors and the three *Krogman* factors are satisfied, the Court need not consider—and a plaintiff need not submit— evidence supporting *Cammer* factor 5").

Nonetheless, Plaintiffs have established this factor. Coffman conducted an event study and a series of statistical analyses to determine whether FibroGen securities reacted to company-specific, new information. Coffman ¶¶ 49-67. This is consistent with the analysis accepted by courts in this district. *See Malriat v. QuantumScape Corp.*, 2022 WL 17974629, at *10 (N.D. Cal. Dec. 19, 2022) (certifying class where expert performed a standard event study showing statistical significant price movements at 90% or 95% levels in response to company specific news and no such movements on days without company specific news).

Coffman analyzed the relationship between FibroGen stock returns on days when it issued earnings announcements and other press releases versus trading days with no news. He concluded that there was "powerful scientific evidence of a cause-and-effect relationship between new publicly released information concerning the Company and changes in the price of FibroGen Common Stock" based on his finding that there was a statistically significant price reaction at the 95% confidence level or greater on nearly 30% of the earnings announcements and other press release dates, but when compared to days with no FibroGen-related news, there was only 3.69% statistically significant reactions. Coffman ¶ 62.

vi. The Krogman Factors and Other Considerations

Courts in this Circuit also consider the three factors from *Krogman v. Sterritt*, 202 F.R.D. 467, 474 (N.D. Tex. 2001): (1) the capitalization of the company; (2) the bid-ask spread of the stock; and (3) the percentage of stock not held by insiders (the "float"). *See, e.g.*, *Petrie v. Elec. Game Card, Inc.*, 308 F.R.D. 336, 349, 356-57 (C.D. Cal. 2015). Here, these factors support a finding that FibroGen securities traded in an efficient market.

The first factor, market capitalization, "may be an indicator of market efficiency because there is a greater incentive for stock purchasers to invest in more highly capitalized corporations." *Krogman*, 202 F.R.D. at 478. During the Class Period, FibroGen's market capitalization averaged

$3.61 billion. Coffman ¶ 69 & Exs. 9-10. Coffman represents that this put FibroGen in the 67th to 80th percentile of the combined NASDAQ and NYSE markets. *Id.* This factor therefore weighs in favor of a finding of market efficiency. *See, e.g.*, *Junge v. Geron Corp.*, 2022 WL 1002446, at *4 (N.D. Cal. Apr. 2, 2022)(finding that an average market capitalization of less than $732 million supports a finding of efficiency).

The second factor is the bid-ask spread, with a narrow bid-ask spreads supporting a finding of efficiency. *See Krogman*, 202 F.R.D. at 478 (noting that a "large bid-ask spread is indicative of an inefficient market"). During the Class Period, FibroGen's stock had a time-weighted average bid-ask spread between 0.034% and 0.133%. Coffman ¶ 72 & Ex. 11. Courts have found higher spreads sufficient to establish efficiency. *See e.g.*, *Petrie v. Elec. Game Card, Inc.*, 308 F.R.D. 336, 349, 356-57 (C.D. Cal. 2015)(certifying class and finding that bid-ask spread of 2.91% supported efficiency); *Radient*, 287 F.R.D. at 574 (bid-ask spread of 0.58% supported efficiency).

Third, when evaluating efficiency, "courts also consider the percentage of shares held by the public rather than insiders" with a large "float" further supporting market efficiency. *Krogman*, 202 F.R.D. at 478. Here, during the Class Period, over 91% of all FibroGen shares were held by non-insiders. Coffman ¶ 73 & Ex. 12. This is consistent with levels courts find sufficient to support a finding of efficiency. *See Purple Mountain Tr.*, 2022 WL 3357835, at *5 (approximately 90% float); *Petrie*, 308 F.R.D. at 357 (approximately 87% float).

Accordingly, the Court finds that Plaintiffs have carried their burden for the presumption of reliance for FibroGen's stockholders during the Class Period.

b. Defendants' Rebuttal of the Presumption of Reliance After April 6, 2021

Although Defendants do not challenge the proof of the elements giving rise to the *Basic* presumption, they do seek to rebut the presumption. Defendants can rebut the presumption through "[a]ny showing that severs the link between the alleged misrepresentation and either the price received (or paid) by the plaintiff, or his decision to trade at a fair market price" including by showing the alleged misrepresentation "did not . . . actually affect the market price." *Id.* at 269. Here, Defendants argue that the alleged misrepresentations had no price impact after April 6, 2021. If true, "then *Basic*'s fundamental premise 'completely collapses, rendering class

certification inappropriate.'" *Goldman Sachs Grp., Inc. v. Arkansas Teacher Ret. Sys.*, 141 S. Ct. 1951, 1959 (2021)(quoting *Halliburton II*, 573 U.S. at 283); *see Halliburton II*, 573 U.S. at 279 ("[*Basic*] affords defendants an opportunity to rebut the presumption by showing, among other things, that the particular misrepresentation at issue did not affect the stock's market price."). Where the presumption does not apply, "individualized issues of reliance ordinarily would defeat predominance and 'preclude certification' of a securities-fraud class action." *Goldman Sachs* at 1959 (first citing *Amgen*, 568 U.S. at 462-63; and then citing *Halliburton II*, 573 U.S. at 281-82).

Defendants challenge the presumption of reliance as to the class period after April 6, 2021. They argue that Plaintiffs are not entitled to the presumption of reliance after this date because no alleged misstatement had any price impact after this date. The only statistically significant drop to FibroGen's stock price after April 6, 2021 occurred on July 16, 2021, so the question before the Court is whether that decline in stock price can be attributed, in whole or in part, to a corrective disclosure. It is critical that the price drop be attributable to a corrective disclosure, because otherwise the "causal link" between the alleged misrepresentation and the price impact will have been severed.

Plaintiffs initially argued that the July 16, 2021 stock price drop was responsive to the disclosure of FibroGen's "prespecified sensitivity analyses" at the FDA's AdCom meeting on July 15. CAC ¶ 103. Defendants responded that two days prior to the July 15, 2021 AdCom meeting, on July 13, 2021 the FDA published a briefing document summarizing the data to be discussed at the AdCom meeting. Defendants claim that the AdCom meeting itself did not involve any new corrections not already revealed in that briefing document. Moreover, at least eight analysts read that briefing document and published reports where they acknowledged this new data on July 13, the day the report was published. Defendants' expert, Dr. Paul Zurek opines that the disclosure of sensitivity analyses on July 13 could not have caused the price decline of July 16. *See In re Qualcomm Inc. Securities Litigation*, 2023 WL 2583306 at *13 (S.D. Cal. Mar. 20, 2023) (finding that disclosure of purportedly omitted information before a stock drop demonstrates a lack of price impact).

Plaintiffs raise three categories of information discussed at the July 15 AdCom they

contend amount to corrective disclosures. In order to carry their burden to rebut the presumption of reliance under *Basic,* Defendants must show either that the disclosures were not corrective or that the corrective disclosures did not cause any part of the price drop on July 16, 2021. The parties agree that even a small price impact would defeat Defendants' rebuttal, though Defendants would have the opportunity to challenge loss causation at the appropriate time.

However, revelations that are not "corrective" cannot form the basis for a corrective disclosure. A finding of "back-end" price impact requires proof that the information disclosed on July 15 was (i) corrective of one or more prior false statements or omissions, (ii) new (unknown to the market prior to July 15), and (iii) "value relevant" (*i.e.,* caused at least some of the stock price decline). *Goldman Sachs Grp., Inc. v. Ark. Tchr. Rtrmt. Sys.*, 141 S. Ct. 1951, 161 (2021); *Basic v. Levison*, 485 U.S. 224, 238, 248 (1998). For example, the AdCom's decision not to recommend approval of Roxa was a development that FibroGen learned about at the AdCom itself, and therefore is not itself a correction of a previous misstatement.[12] This is so even if the AdCom action was based on a prior corrective disclosure. AdCom's decision cannot form the basis for a back-end price impact. Accordingly, the Court evaluates the three alleged corrective disclosures in turn.

i. Upper Bound Hazard Ratio

The first allegedly corrective disclosure relates to the acceptable upper bound hazard ratio, or non-inferiority margin, relevant to the FDA's analysis of Roxa. Reply at 3, 7-8. A non-inferiority margin is a pre-specified value during clinical trials and defines the maximum acceptable difference between a new treatment and an existing treatment. It is used to determine that a new treatment is not worse than the existing treatment. Therefore, a lower non-inferiority margin would make harder for Roxa to be found to be at least as good as Epogen, the existing standard of care. Plaintiffs allege that investors learned for the first time at the AdCom meeting that the FDA had specifically rejected a non-inferiority margin of 1.3, and instead wanted the applicable margin to be set at 1.25.

[12] Indeed, Defendants contend that it was the Advisory Committee's vote to recommend not to approve Roxadustat that caused the entire stock price decline on July 16, 2021.

The prespecified sensitivity analysis, which was disclosed in the pre-AdCom briefing document on July 13, showed that Roxa "exceeded both the 1.25 and 1.3 margins." CAC ¶¶ 175, 183, 204, 228. While the sensitivity analysis was disclosed ahead of the meeting, the revelation that the FDA had rejected the 1.3 margin apparently came at the AdCom meeting itself, and allegedly contradicted FibroGen's prior representations about the margin. Reply at 8. Plaintiffs assert that "analysts specifically highlighted this new information, stating: "despite multiple previous assertions from FibroGen that an upperbound hazard ratio (HR) limit of 1.3 would be approvable, the [AdCom] confirmed that FDA had not agreed to this and in fact preferred 1.25 as an upper-bound." Kaplan Decl., Ex. 20.

As an initial matter, it is undisputed that the prespecified sensitivity analysis, which was disclosed with the July 13 briefing document, showed that Roxa had exceeded even the 1.3 margin. Therefore, it was already public knowledge that Roxa would likely fail regardless of which of the two margins the FDA adopted. On that basis alone, this disclosure was likely immaterial to investors after the July 13 briefing document was published.

Furthermore, Defendants contend that this allegedly corrective disclosure fails both because it is not "corrective" and because it is not "new." It is not corrective because, as the Court acknowledged in its MTD Order, Plaintiffs did not plausibly allege that FibroGen told investors that the FDA had agreed to an upper bound of 1.3. In the Court's Motion to Dismiss order, the Court found that while "none of the relevant alleged statements imply an agreement with the FDA regarding the non-inferiority margin ..... allegations that data was manipulated to conform to these margins survive." *See In re FibroGen, Inc.*, 2022 WL 2793032, at *17-18 (N.D. Cal. July 15, 2022). Moreover, Defendants allege that the FDA had not directly rejected the 1.3 non-inferiority margin prior to the AdCom meeting. Specifically, Defendants point out that the FDA used the present tense when referring to their rejection of that margin at the AdCom meeting:

> I'll note the applicant and FDA did not agree prospectively on a risk margin. Furthermore, we do not agree with the applicant's proposed margin of 1.3, as it was defined after results of the study were known. Therefore, FDA does not agree on the interpretation of the results using strictly a noninferiority hypothesis testing approach. Rather, our interpretation of the trial findings focuses on the estimation of MACE risk and the uncertainty around it.

AdCom Meeting Transcript ("AdCom Tr."), Docket No. 221-1, Ex. A at 166:3-12. This quote from the AdCom does imply that the FDA rejected the margin of 1.3 in part because it was defined after results of the study were known, which Plaintiffs characterize as evidence of Defendants' manipulation of the data. However, Plaintiffs do not contend that this is the first time the market learned about the manipulations themselves. Rather, this is when the market learned about the FDA's reaction, a fact which cannot properly be characterized as a corrective disclosure because it was not previously known to Defendants and did not contradict a previously uncorrected misstatement. Accordingly, the Court finds that the FDA's statements about the hazard ratio/non-inferiority margin did not amount to a corrective disclosure and therefore could not have caused the relevant price impact.

ii. Dose Mitigation Strategy

Plaintiffs allege that at the AdCom, investors first learned that Defendants' dose mitigation strategy was not viable for three principal reasons: (i) there was an "alarmingly negative" link between higher doses of Roxa and death, including a "dose dependent increase in mortality," and FibroGen's own clinical data for Roxa was not "particularly conclusive," Kaplan Decl., Ex. 17 at 2; AdCom Tr. at 256:2-258:8; (ii) FibroGen had "no clear evidence that [its] mitigation strategy would influence other [adverse safety] events" beyond thrombosis, such as sepsis. *Id.* at 132:19–133:19; and (iii) FibroGen had only recently proposed this strategy with the FDA, and thus the agency would not be able to properly evaluate it as part of the NDA. *Id.* at 187:8-14.

Defendants counter that the AdCom's and the FDA's reaction to the dose mitigation strategy could not have corrected any misstatements, first because the July 13 briefing document disclosed the fact that FibroGen had proposed a dose mitigation strategy but did not yet have clinical data to support it. For this, Defendants cite several analyst reports published in response to the July 13 briefing document but before the AdCom meeting. *See, e.g.*, Brien Decl., Ex. 8 at 12 ("the applicant speculates that thromboembolic risks might be reduced through use of a lower Roxadustat starting dose. Their prediction seems plausible, but is unproven."). This suggests that analysts understood that the dose mitigation strategy was unproven prior to the AdCom meeting. *Id.*, Ex. 10 at 1 ("the briefing documents suggest the FDA does not believe these lower doses with

an appropriate titration scheme have been sufficiently tested..... "); D's Ex. 12 at 1 ("we do not expect the panel to be supportive of approval until evidence for proposed thrombosis risk mitigation strategies are generated." D's Ex. 14.).

Moreover, Plaintiffs have not alleged that any of the data discussed at the AdCom meeting was not already disclosed in the July 13 briefing document. The briefing document made clear that FibroGen lacked clinical data directly testing the dose mitigation strategy, and disclosed the data in FibroGen's possession that indicated whether the strategy was worth pursuing. Investors had access to the same information the FDA relied upon in rejecting the dose mitigation strategy. The FDA's characterization of that data on July 15 was not available to investors, nor to FibroGen, before the AdCom itself, and was therefore not a "corrective disclosure."

Accordingly, any "correction" relating to the dose mitigation strategy was disclosed to investors before the AdCom meeting. The AdCom's discussion of the dose mitigation strategy accordingly did not amount to a corrective disclosure.

iii. Differential Dropout Rate of Study Participants[13]

Plaintiffs claim that the AdCom revealed serious issues with FibroGen's data analyses, and that a statistical expert on the AdCom's panel warned that FibroGen's analyses were "hope[lessly] confounded" and "fundamentally broken" because most were not based on the standard intention to treat ("ITT") window, which Defendants had previously touted as a "conservative" test. AdCom Tr. at 277:4-278:10; ECF No. 196-1 at Statement 8. FibroGen believed that the alternative to ITT, (the "on treatment" or "OT-7" approach), was improperly biased against Roxadustat, because non-dialysis dependent patients in the placebo arm (those who were not

[13] Defendants contend that Plaintiffs have waived this alleged corrective disclosure by failing to raise it before the supplemental briefing. Waiver is the intentional relinquishment of a known right with knowledge of its existence and the intent to relinquish it." *United States v. King Features Entertainment, Inc.*, 843 F.2d 394, 399 (9th Cir. 1988). "An implied waiver of rights will be found where there is 'clear, decisive and unequivocal' conduct which indicates a purpose to waive the legal rights involved." *United States v. Amwest Surety Ins. Co.*, 54 F.3d 601, 602–03 (9th Cir.1995) (quoting *Groves v. Prickett*, 420 F.2d 1119, 1125 (9th Cir.1970). Defendants have not demonstrated that Plaintiffs actions in failing to raise this corrective disclosure amounted to a decisive and unequivocal waiver. Moreover, Plaintiffs reference both the differential dropout rate and the ITT analysis in their complaint. CAC ¶¶ 53, 168. Therefore, the Court finds that Defendants are not prejudiced by Plaintiffs' characterization of this revelation as a corrective disclosure.

receiving any treatment for their anemia) tended to drop out of the study much earlier than patients receiving treatment with Roxadustat, which resulted in an artificially low number of major adverse cardiovascular events for that group compared with the treatment group. Oppo. at 10-11. Therefore, after unblinding the results, FibroGen proposed an ITT method for the non-dialysis dependent population. *Id.* The ITT method includes even those did not ultimately receive the original treatment they were categorized for in the statistical analysis, meaning that patients who were assigned to the placebo group but later received a treatment would be evaluated with the placebo group nonetheless. Plaintiffs characterize this after the fact application of ITT methodology as a retroactive manipulation of the study, while Defendants represent that ITT is an accepted method for presenting safety data. *Id.* at 9. Indeed, the FDA indicated its agreement with FibroGen that the ITT methodology was more appropriate in this instance. Brien Decl., Ex. 8 at 8, 48.

The AdCom noted that "around 10 percent missing data for mortality or survivorship, which is quite surprising given the illness of this cohort," which rendered FibroGen's ITT analysis not "a true ITT analysis." AdCom Tr. at 188: 5-18 & 279:9-10. Moreover, the AdCom revealed that the ITT analysis used as a primary analysis for the NDD population was also not viable. Specifically, while the ITT analysis was purportedly designed to solve a differential dropout issue between the Roxadustat and placebo groups, Defendants revealed during the AdCom that they lacked data for nearly 10% of the patients enrolled in the NDD trials. AdCom Tr. at 279:11-13. Plaintiffs argue that even if FibroGen's ITT analyses contained complete data, AdCom members stated that the dropout issue still could not explain the entire difference in MACE and all-cause mortality in the pooled NDD analyses between the ITT and OT-7 windows. However, the July 13, 2021 included the underlying data, which showed that "[o]verall, 87.8% and 91.4% of patients had complete follow-up for MACE and vital status, respectively. Kaplan Decl., Ex.18 at 48. The number of patients who had complete follow-ups represents the ones for whom data was not missing, leaving approximately 10% of patients with missing data. The 10% figure was implicitly disclosed in the July 13 briefing document because it could be inferred from the data that was presented. The Court therefore concludes that the data had been disclosed and was not a new

disclosure at the AdCom meeting. It could not have served as a "corrective disclosure."

Accordingly, the Court finds that FibroGen has carried its burden to rebut the presumption of reliance by a preponderance of the evidence. The Court finds that the portion of the proposed class after April 6, 2021 is not proper for certification due to a lack of predominance because Plaintiffs in this period would need to individually allege reliance and not Fraud on the Market.

2. Damages

At this stage, Plaintiffs' burden regarding damages is merely to "'show that their damages stemmed from the defendant's actions that created the legal liability' under the proposed damages model." *Apple*, 2022 WL 354785, at *10 (quoting *Leyva v. Medline Indus. Inc.*, 716 F.3d 510, 514 (9th Cir. 2013)). Defendants contend that Plaintiffs have failed to meet their burden of proving that damages can be calculated on a class-wide basis in a way that is consistent with their theory of liability, as required by the Supreme Court's decision in *Comcast*, 569 U.S. at 27. Specifically, they claim that Plaintiffs' expert spends only six paragraphs of his report discussing his damages opinion, and that those paragraphs are merely boilerplate because they do not mention any fact relating to this case. Coffman Report ¶¶ 93-98.

Defendants submit that this discussion fails to satisfy *Comcast* because it does not adequately describe Plaintiffs' theories of liability, nor how those theories are consistent with his proposed damages methodology. Defendants assert that this problem applies to the entire class period, but with particular force when it comes to the class period after April 6, 2021, because they argue there was no price impact after that date at all. *See* Opp. 21; Zurek ¶¶ 48-56 & nn.86-87. Plaintiffs counter that each Class member suffered damages traceable to the alleged misstatements and omissions and corrective disclosures on May 9, 2019, March 1, 2021, April 6, 2021, and July 15, 2021. *Id.* ¶¶ 263-67. Coffman described the "out-of-pocket" damages methodology Plaintiffs plan to use to calculate damages on a class-wide basis and conducted an event study and regression analysis quantifying abnormal returns related to the fraud. Coffman Rep. ¶¶ 46-78. He further explained how the out-of-pocket method can be applied to measure damages tied to Defendants' liability. *Id.* ¶¶ 93-94.

The out-of-pocket method "states that damages are equal to the artificial inflation in the

share price at the time of purchase minus the artificial inflation per share at the time of sale." *Id.* ¶ 93.[14] This is intended to account for the fact that part of the investment income from FibroGen was attributable to market growth or inflation, rather than the alleged fraud. Plaintiffs also point out that several other courts have accepted Coffman's same damages methodology. *See, e.g.*, *Police Ret. Sys. of St. Louis v. Granite Constr. Inc.*, 2021 WL 229310, at *7 (N.D. Cal. Jan. 21, 2021) ("out-of-pocket method will be suitable and fulfills the damages element of Rule 23(b)"); *Milbeck v. TrueCar, Inc*., 2019 WL 2353010, at *4 (C.D. Cal. May 24, 2019) ("Various courts have considered the same Coffman report as that offered in this case and have found it sufficient"); *Weiner v. Tivity Health, Inc.*, 334 F.R.D. 123, 137 (collecting cases and concluding that Coffman's out-of-pocket method was sufficient).

The most common methodology to quantify artificial inflation is to perform an event study that measures price reactions to corrective disclosures. Such an event study would also need to consider whether and to what extent any non-fraud related information (*i.e.* "confounding information") contributed to the observed price movement." *Id.* ¶ 96. If there is confounding information, disaggregating the price impact of corrective disclosures may depend on information learned through discovery. Coffman then provides some examples of how to disaggregate the confounding information, and states that "[r]egardless of the technique used, it is performed on a class-wide basis – in other words, the specific methodology applies regardless of the identity or circumstances of any individual class member." *Id.*

One method for performing the event study is "to estimate a regression model over some period of time (an "estimation window") to observe the typical relationship between the market price of the relevant security and broad market factors." *Id.* ¶ 50. A "regression" or "regression

[14] Shares that are not sold before the full revelation of the fraud would be subject to the Private Securities Litigation Reform Act of 1995's ("PSLRA") "90-day lookback" provision, which states that "…in any private action arising under this title in which the plaintiff seeks to establish damages by reference to the market price of a security, the award of damages to the plaintiff shall not exceed the difference between the purchase or sale price paid or received, as appropriate, by the plaintiff for the subject security and the mean trading price of that security during the 90-day period beginning on the date on which the information correcting the misstatement or omission that is the basis for the action is disseminated to the market." *See* Private Securities Litigation

Reform Act of 1995, dated December 22, 1995, 737, 748-49. *Id.* n103.

model" is a statistical technique for measuring the ability of one or more variables (the "independent variables") to "explain" another variable of interest (the "dependent variable"). In this case, the daily percentage change in FibroGen Common Stock (the FibroGen daily return) is the dependent variable and the contemporaneous daily returns for a market and industry index are the independent variables. For a general discussion of regression analysis, see Damodar N. Gujarati, Basic Econometrics, McGraw Hill, Chapters 1-3 (3rd ed. 1995). *Id.* n49. In this case, Coffman's regression analysis evaluates "the relationship between FibroGen Common Stock's daily returns (percentage change in price) controlling for the S&P 500 Total Return Index (the "Market Index") and the Nasdaq Biotechnology Total Return Index." *Id.*

Defendants' argument that the July 16, 2021, stock price decline was not in response to any corrective information does not impact whether Coffman's out of pocket cost model can be used to calculate damages on a class-wide basis. *See Apple*, 2022 WL 354785, at *12 (rejecting defendants' attacks on plaintiffs' damages model based on the purported lack of "fit between an alleged corrective disclosure and a prior alleged fraudulent statement," finding that this argument amounts to "nothing more than [ ] attack[s] on loss causation, which plaintiff need not show as a condition of class certification."). Defendants also argue that Plaintiffs assert a "materialization of the risk theory" in connection with the final corrective disclosure, rather than Coffman's out-of-pocket" damages methodology. Opp. at 21-22, n.11. Plaintiffs assert that this, too, is a premature loss causation argument. Reply at 19. Judge Alsup recently agreed with this characterization, writing that "materialization of the risk is not a theory of liability. It is a form of loss causation." *Junge v. Geron Corp.*, No. C 20-00547-WHA, 2022 WL 1002446, at *8 (N.D. Cal. Apr. 2, 2022). He went on to say that "[t]he possible existence of such a theory does not contravene *Comcast* or defeat predominance." *Id.* Accordingly, Plaintiffs have met the predominance requirements of Rule 23(b) for the portion of the class ending on April 6, 2021.

For the class period after April 6, 2021, Plaintiffs have not provided a theory of damages that can be calculated on a class-wide basis. In addition to the Court's conclusion that the class cannot be certified for the period after April 6, 2021, Plaintiffs have failed to propose a methodology that could separate the portion of the July 16, 2021 decline in stock price that is

attributable to any corrective disclosures from the portion that is attributable to the AdCom's ultimate decision not to recommend approval for Roxa. Even if the Court had found that there were corrective disclosures on July 15, 2021, it is obvious that a large majority of the stock price decline the following day is attributable to that announcement. Without a method to calculate damages that takes this into account, the Court cannot find that the Plaintiffs have carried their burden as to this factor. Accordingly, for this further reason, the Court declines to certify the portion of the class that purchased FibroGen securities after April 6, 2021.

3. Superiority

Defendants do not contest whether a class action is superior to other available methods of litigation. Here, the class members' interests in individually controlling the prosecution or defense of separate action, the extent that other similar litigation has begun, the desirability of concentrating the litigation in this forum, and the likely difficulties in managing a class action all favor class litigation here. *See* Fed. R. Civ. Proc. 23(b)(3)(A)-(D). This action meets the superiority requirement of the federal rules.

C. Appointment of Class Counsel

Defendants do not contest that class counsel is adequate. For adequacy of class counsel, the Court looks to "(i) the work counsel has done in identifying or investigating potential claims in the action; (ii) counsel's experience in handling class actions, other complex litigation, and the types of claims asserted in the action; (iii) counsel's knowledge of the applicable law; and (iv) the resources that counsel will commit to representing the class." Fed. R. Civ. Proc. 23(g)(1)(A). Saxena White are experienced class action litigators who have dedicated a substantial amount of time and resources to this case. Counsel are competent and qualified, and have no conflicts of interest with any class members. The requirements of Rule 23(g) are therefore satisfied.

D. Class Certification as to Options Holders

The inclusion of FibroGen options holders in the certified class raises two distinct questions. First, whether Plaintiffs are entitled to the presumption of reliance in the market for FibroGen options, and second, whether Plaintiffs have proposed a theory of damages to options holders that can be calculated on a class wide basis.

1. Presumption of Reliance for Options Holders

Plaintiffs assert, and Defendants do not contest, that if Plaintiffs carry their burden on the presumption of reliance with respect to FibroGen stock, the Court should presume reliance in the market for FibroGen options as well. Motion at 31-32. This is because "[t]he market price for options is directly responsive . . . to changes in the market price of the underlying stock, and to information affecting that price." *Deutschman v. Beneficial Corp.*, 841 F.2d 502, 504 (3d Cir. 1988). Plaintiffs' expert performed a "standard put-call parity evaluation" to evaluate the efficiency of the market for FibroGen stock options during the Class Period. *See* Coffman Rep. ¶¶ 86-92 & Exs. 14-17. Based on his analysis, Coffman concludes that FibroGen's options contracts traded in an open, developed, and efficient market during the Class Period. *Id.* ¶ 92; *see Rougier v. Applied Optoelectronics, Inc.*, 2019 WL 6111303, at *14 (S.D. Tex. Nov. 13, 2019) (finding market efficiency for common stock is sufficient to prove options market efficiency where put-call parity test also demonstrated that options traded in an efficient market). Defendants' expert does not address the options market, nor does he counter Coffman's analysis. *See generally* Zurek Rep.

Plaintiffs cite no in-circuit precedent for the assertion that an efficient market for options can be presumed solely from a finding of an efficient market for common stock. Indeed, a court in this District recently questioned the validity of that assumption. *See In re Apple Inc. Securities Litigation*, 2022 WL 354785, at *13 n11 (N.D. Cal. Feb. 4, 2022). Nonetheless, the Court finds Coffman's analysis sufficient to make a *prima facie* showing that the market for FibroGen options was efficient during the proposed Class Period.

2. Calculation of Damages for Options Holders

Plaintiffs must propose a theory of damages that could be used on a class-wide basis with respect to the options market in order to prevail in their motion to certify that portion of the class. *See Apple* at *13 (declining to include options holders as part of a certified class because plaintiffs had not shown that individualized issues pertaining to damages to options holders would not predominate given the varying characteristics of the distinct stock options available during the class period). In *Apple*, there were 2,282 distinct types of stock options available for trading during the proposed class period. In the instant case, Coffman represents that "[d]uring the Class

Period, a total of 592 call option series and 592 put option series were listed [and of those,] 421 call option series and 386 put option series had non-zero trading volumes during this period." Coffman Rep. ¶ 82. Neither party has presented evidence relating to distinct characteristics of these options series.

Coffman discusses the analysis he used to evaluate whether FibroGen options prices reacted to the corrective disclosures *at all* in support of his *Cammer* factor five analysis. However, he does not represent that this method could be used to calculate damages on a class-wide basis. He writes:

> The price of an option can change based on a number of factors even if the price of the underlying stock is constant. These factors include, but are not limited to, the level of the stock price in relation to the strike price, time to maturity, and volatility. Therefore, I utilize the well-known and standard Black-Scholes pricing model, along with the expected changes in FibroGen stock price based upon the regression analysis described in Section VI to quantify the expected price movement for an individual option series on each relevant date. In other words, by using the FibroGen Common Stock expected return and the Black Scholes formula, I control for option price movements expected based upon changes in the Market Index, Industry Index, and the value of other factors in the Black Scholes Model including the strike price, time to maturity, risk free rate of interest, and volatility of FibroGen Common Stock.

Id. ¶ 88.

The Court lacks sufficient factual background regarding the options available for sale during the class period to determine whether damages can be calculated on a class-wide basis. Accordingly, the parties are **ORDERED** to submit supplemental briefing relating to calculation of damages on a class-wide basis for options holders. Defendants are to submit a supplemental brief of no more than ten (10) pages within two weeks of this order, and Plaintiffs are to submit a responsive brief of no more than ten (10) pages one week after that.

V. CONCLUSION

For the foregoing reasons, Plaintiffs' motion to certify this class is **GRANTED in PART**. The class is certified as to shareholders for the Class Period from December 20, 2018, through April 6, 2021. Plaintiffs' motion to appoint class representatives and class counsel is **GRANTED**. The Court reserves a decision as to class certification for options holders for the Class Period from

December 20, 2018, through April 6, 2021. The parties' motions to seal are **GRANTED**.

At this juncture, the Court instructs the Clerk of the Court to file this order, in its entirety, under seal. The Court orders the parties to meet and confer to determine which portions of this order may be publicly filed. The parties shall jointly file their request to file under seal within a week of the date of this order.

This order disposes of Docket Nos. 147, 149, 175, 178, 179, 184, 189, 191, 196, and 204.

IT IS SO ORDERED.

Dated: October 3, 2023

EDWARD M. CHEN
United States District Judge